

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES JUN 17 P1:38

In the Matter of)
)
ECUMED HEALTH GROUP) ADMINISTRATIVE COMPLAINT
a corporation,) FOR CIVIL MONEY PENALTY
)
and)
)
AMADOR REYES,) FDA Docket: 2004H-0322
JUAN C. CARRAI,)
RICHARD W. STONE, M.D., and)
ERLINDA E. ENRIQUEZ, M.D.,)
individuals.)
)

COMPLAINANT'S DOCUMENTARY EVIDENCE
AND EXHIBIT LIST

Pursuant to the Court's Order dated February 22, 2005, Complainant, the Center for Devices and Radiological Health, Food and Drug Administration, files this list of its documentary evidence and written direct testimony. All exhibits below were filed on June 10, 2005, with Complainant's Memorandum In Support Of A Motion For Partial Summary Decision, and are not attached hereto. Upon request, Complainant will supply a new set of those exhibits.

Pursuant to 21 C.F.R. § 17.39(g), Complainant reserves the right to request an opportunity to introduce rebuttal witnesses, including Timothy Couzins and Pricilla Butler, and rebuttal evidence.

2004H-0322

LST 2

<u>Exhibit No.</u>	<u>Document</u>
G-A	Declaration of Michael P. Divine, M.S. (June 10, 2005)
G-A(1)	Letter from FDA to Dr. Stone at Ecumed Health Group, 687 E. 9 St. Hialeah, FL 33010 (June 13, 2001)
G-A(2)	Mammography Quality Standards Act Six-Month Provisional Certificate Fact Sheet
G-A(3)	Provisional MQSA Certificate (expiration date: December 8, 2001)
G-A(4)	Letter from ACR to Dr. Stone at Ecumed Health Group, 687 E. 9 St. Hialeah, FL 33010 (September 14, 2001)
G-A(5)	Letter from FDA to Dr. Stone at Ecumed Health Group, 687 E. 9 St. Hialeah, FL 33010 (November 1, 2001)
G-A(6)	Mammography Quality Standards Act Expiration of Certificate (Provisional) Fact Sheet
G-A(7)	Letter from ACR to Dr. Stone at Ecumed Health Group, 687 E. 9 St. Hialeah, FL 33010 (November 14, 2001)
G-A(8)	Ecumed Health Group's appeal of ACR's denial of accreditation (December 7, 2001)
G-A(9)	Letter from ACR to Dr. Stone at Ecumed Health Group, 687 E. 9 St. Hialeah, FL 33010 (January 4, 2002)
G-A(10)	Ecumed Health Group Application for Reinstatement
G-A(11)	Quality Control Test
G-A(12)	Letter from FDA to Janet Labrada, Ecumed Health Group (May 7, 2003)

G-A(13) Letter from FDA to Dr. Enriquez at Ecumed Health Group, 687 E. 9 St. Hialeah, FL 33010 (May 9, 2003)

G-A(14) Ecumed Health Group Certificate History Report

G-B Declaration of D. Janneth Caycedo (June 3, 2005)

G-B(1) April 2003 Establishment Inspection Report of Ecumed Health Group

G-B(2) Affidavit of Juan C. Carrai (April 24, 2003)

G-B(3) Ecumed Health Group Patient Logs between and including January 2003 to April 2003

G-B(4) FDA Investigation Memorandum for Ecumed Health Group (July 2, 2003)

G-B(5) Affidavit of Amador Reyes (June 26, 2003)

G-B(6) Ecumed Health Group Patient Logs between and including January 2002 to December 2002

G-B(7) Ecumed Health Group Mammography Reports between and including January 2002 to April 2003

G-C Florida Uniform Business Report for year 2001, 2002, and 2003

Respectfully submitted,



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CERTIFICATE OF SERVICE

I certify under the penalty of perjury that on this 17th day of June, 2005, I served a copy of "Complainant's Documentary Evidence and Exhibit List" via facsimile and regular U.S. mail on the following:

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